

REMARKS

Status of the Claims:

Claims 5-6, 23-24, 36-66, and 71 are canceled without prejudice or disclaimer, claims 1-4, 7-22, 25-35, and 67-70 are currently amended, and new claims 72-74 are added. These amendments are made without prejudice or disclaimer and Applicants reserve the right to pursue any canceled subject matter in one or more continuing applications with the same rights of priority as the instant application.

The new claims find support in original claim 18 and the as-filed specification; thus, no new matter is added.

Upon entry of these amendments, claims 1-4, 7-22, 25-35, 67-70, and 72-74 will be pending. These claims are presented for reconsideration.

Amendments to the Specification:

As requested by the PTO, the first line of the specification has been amended to replace "based on" with "claims benefit of." *See* Office Action, page 3, item 5.

The specification has also been amended at page 11, lines 26 and 28 to remove the embedded hyperlink per MPEP §608.01. *Id.*

The "Summary of the Invention" is objected to because it allegedly contains claim language. *Id.* With respect, the objection appears contrary to MPEP §608.01(d), which states that the "summary should be consistent with the subject matter of the claims". Therefore, using the same language as is found in the claims is consistent with MPEP §608.01(d) as well as 37 C.F.R. § 1.73, and should not be objectionable. Accordingly, Applicants respectfully request withdrawal of the objection.

Claim Objections:

Claims 2-4, 6-17, 18-22, 24-35, 63-66, and 70 are objected to for various informalities. Office Action, pages 3-4, item 6. Applicants respond to these objections in turn below.

Claim 18 is objected to for allegedly embracing non-elected sequences. While Applicants provisionally elected SEQ ID NO: 6, Applicants maintain that the Restriction Requirement was improper. Indeed, in view of generic claim 1, the Restriction Requirement falls squarely under an example of an *improper* restriction recently published with the proposed rules for Examination of Patent Applications That Include Claims Containing Alternative Claim Language, 72 Fed. Reg. 44,992 – 5,001 (Aug. 10, 2007). As set forth at page 44,995, columns 2-3, “[a]s a general principle, a claim that encompasses more than one species, but does not list alternatives, defines one generic invention.” Thus, “dividing one generic claim by restriction *may not be appropriate*,” although “making a requirement for an election of species . . . would be permissible.” Because generic claim 1 links the sequences recited in claim 18, restriction between the sequences is improper, and claim 18 has not been amended to cancel the other sequences.

Claims 63 and 68-69 are objected to for allegedly depending on a non-elected claim. Applicants have canceled claim 63 and amended claims 68-69 to be independent claims which incorporate the features of previous claim 50.

Claims 2-4 and 6-17 are objected to for reciting "A method" rather than "The method." The present version of the claims avoids this issue.

Claim 19 is objected to for reciting "Transgenic" rather than "A transgenic." Similarly, claims 20-22 and 24-35 recite "Transgenic" rather than "The transgenic." The present version of claims 19, 20-22, and 24-35 avoids this issue.

The phrase "nucleic add" has been amended to read "nucleic acid" in claims 1 and 19.

Claims 64-66 are objected to for reciting "A method" rather than "The method." The present version of the claims avoids this issue.

Claim 70 is objected to for reciting "Plant" rather than "A plant." The present version of claim 70 avoids this issue.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of all claim objections.

Rejections under 35 U.S.C. § 112, second paragraph:

Claims 18 and 70 were rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Office Action, pages 4-5, item 8.

Specifically, claim 18 is rejected because it recites "a nucleic acid sequence that is complementary". Applicants believe the present version of claim 18 avoids the PTO's concerns and therefore request that the rejection be withdrawn.

Claim 70 is rejected because it is allegedly unclear if the claimed plant seeds comprise the chimeric nucleic acid sequence using a method of claim 63. The present version of claim 70 depends from claim 1 rather than claim 63, and so is believed to avoid this issue. Moreover, Applicants note that it was clear at the time of filing that a plant seed obtained from a plant and prepared according to the method of claim 1 would comprise the chimeric nucleic acid sequence, as the chimeric nucleic acid sequence is introduced into the plant cell and expressed in seed.

Rejections under 35 U.S.C. § 112, first paragraph:

A. Written Description

Claims 1-4, 6-35 and 63-70 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action, pages 5-7, item 10.

Specifically, the PTO alleges "Applicants do not describe the genus of isolated seed-specific promoters that have substantial sequence homology to SEQ ID NO: 6 or is an analog of SEQ ID NO:6, or hybridizes to a nucleic acid sequence under stringent conditions to a nucleic acid molecule have the sequence of SEQ ID NO: 6 as broadly claimed." *Id.* Furthermore, the PTO takes the position that "Applicants do not describe the genus of the seed-specific promoters isolated from flax comprising a promoter element selected from the

group of promoter elements consisting of the RY repeat, ABRE, EBOX, and SEF3.” *Id.* Applicants respectfully traverse the grounds for this rejection.

The written description requirement requires that “the specification shall contain a written description of the invention.” 35 U.S.C. § 112 (2006). The written description requirement ensures “that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent’s term.” MPEP § 2163. As explained in MPEP § 2163, “to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention” MPEP § 2163 (citing *Moba, B. V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 U.S.P.Q.2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1563, 19 U.S.P.Q.2d 1116 (Fed. Cir. 1991)).

The “fundamental factual inquiry” for written description “is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.” MPEP § 2163.02 (citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-1564, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991)). “Possession may be shown in a variety of ways including description of an actual reduction to practice...or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.” MPEP § 2163.02.

At the outset, independent claims 1, 19, and 68-69 are presently amended to specify that the seed-specific promoter comprises an RY repeat and an ABRE promoter element. As the Examiner has noted, in *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), “the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus”. Here, the present application discloses four seed-specific promoters that contain both an RY repeat and an ABRE promoter element. The nucleic acid sequences of the four promoters are provided in the application in SEQ ID NO:1, SEQ ID NO:4, SEQ ID NO:6, and SEQ ID NO:8.

Therefore, the as-filed specification describes a representative number of nucleotide sequences (*e.g.* SEQ ID NOs:1, 4, 6, and 8) as well as the structural features common to the members of the genus (*e.g.* an RY repeat and ABRE promoter element) for the seed-specific promoters defined in the claims. Accordingly, Applicants have properly described the genus of seed-specific promoters recited in the claims.

With regard to the rejection of claim 18, the PTO submits that the specification does not describe the genus of isolated seed-specific promoters that have substantial sequence homology to SEQ ID NO: 6, or is a complement of SEQ ID NO: 6. Office Action, page 6. Applicants respectfully traverse the grounds for this rejection.

The PTO's SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES provides an example of a claimed invention that satisfies the written description guidelines for the genre of "hybridization language," including complements and analogs. Specifically, hypothetical claim 1 recites, "An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1, wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity." See Example 9, pages 35-37.

The PTO maintained that the hypothetical claim is drawn to "a genus of nucleic acids all of which must hybridize with SEQ ID NO: 1 and must encode a protein with a specific activity." See Example 9, page 36. Furthermore, the PTO asserted "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention." See Example 9, pages 36-37. Based on the PTO's own analysis, the PTO concluded that hypothetical claim 1 is adequately described. See Example 9, page 37.

Applying the PTO's own standards to the instant invention, Applicants submit, compels a conclusion that the present claim 18 satisfies the written- description requirement. In particular, claim 18 recites specific *structural* and *functional* language characterizing the

claimed polynucleotide sequences. Additionally, Applicants submit that they are entitled to sequences that hybridize to a nucleic acid of SEQ ID NOS:1, 4, 6 and 8 under stringent hybridization conditions, and claim 18 has been amended to recite sequences that hybridize to a specified sequence under stringent hybridization conditions which comprise hybridization at 5 x sodium chloride/sodium citrate (SSC) x Denhardt's solution/1.0% SDS at T_m -5°C, followed by a wash of 0.2 x SSC/0.1% SDS at 60°C (the stringent hybridization conditions set forth on page 12, lines 31-34 of the application). The PTO's Written Description Guidelines and the Federal Circuit decision in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002), both indicate that "stringent hybridization" claims such as instant claim 18 satisfy the written description requirement. Example 9 of the Written Description Guidelines explains that hybridization under stringent conditions yields structurally similar molecules, such that the disclosure of a single species within the recited genus (e.g., the base sequence) is sufficient to support a claim to the genus. In *Enzo*, the Federal Circuit discussed this example from the Guidelines with approval. *Enzo*, 323 F.3d at 967. Because both the Guidelines and *Enzo* are binding on the PTO, the written description rejection of claim 18 should be withdrawn.

B. Enablement

Claims 1-4, 6-35, and 63-70 are rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. Office Action, pages 7-9, item 11. The PTO takes the position that the specification, while being enabling for a method of using an isolated nucleic acid molecule comprising a nucleic acid sequence comprising bases 1-417 of SEQ ID NO: 6 having seed-preferred promoter activity and a transgenic plant transformed therewith, does not reasonably provide enablement for a method of using a nucleic acid homolog, a nucleic acid analog or an isolated nucleic acid molecule that hybridizes under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 8. Applicants respectfully traverse the grounds for this rejection.

As mentioned above, the independent claims now recite that the seed-specific promoter comprises an RY repeat and an ABRE promoter element. Applicants have provided four examples of seed-specific promoters that comprise these elements. Therefore,

Applicants have taught how to make and use the genus of seed-specific promoters recited in the instant claims.

With respect to SEQ ID NO: 6, the as-filed specification enables sequences that are complementary, sequences that have substantial sequence homology, and sequences that are analogs of SEQ ID NO:6. With respect to sequences that hybridize under stringent conditions to recited sequences, the application as filed provides sufficient guidance to enable one of skill in the art to prepare such sequences. That is, only a routine amount of work would be required for someone skilled in the art to design suitable sequences and assess their hybridization under the recited stringent hybridization conditions.

In view of the foregoing, we respectfully request that all of the rejections to the claims under 35 USC §112, first paragraph, as lacking enablement, be withdrawn.

Rejections under 35 U.S.C. § 102:

Claims 1-3, 14-17, 18-21, 33-35, 63-65, and 67-70 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Jain *et al.* (WO 98/18948, published 7 May 1998). Office Action, pages 9-10, item 12. As mentioned previously, the claims have been amended to specify that the seed-specific promoter comprises an RY repeat and an ABRE promoter element. In contrast, the flax promoters disclosed in Jain (1) are not seed specific and (2) do not contain an RY repeat. As a result, Jain does not anticipate the claims.

In view of the foregoing, we respectfully request that all of the rejections to the claims under 35 U.S.C. §102(b) be withdrawn.

Rejections under 35 U.S.C. § 103:

Claims 4, 22, and 66 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Jain *et al.* Office Action, pages 10-11, item 14. As stated above, Jain *et al.* does not teach (1) a seed-specific promoter or (2) a promoter comprising an RY repeat. The PTO takes the position that it would be obvious to transform safflower based on the teachings of

Jain. However, as Jain does not teach the seed-specific promoters of the present invention, there is no prima facie case of obviousness.

In view of the foregoing, we respectfully request that all of the rejections to the claims under 35 U.S.C. §103 be withdrawn.

Double Patenting:

Claim 18 is rejected on the ground of nonstatutory obviousness-type double patenting over claim 1 of U.S. Patent No. 6,777,591. Office Action, page 12, item 17. Applicants respectfully defer this issue until the application is otherwise in condition for allowance.

CONCLUSION

In view of the foregoing, we respectfully submit that the application is in order for allowance and early indication to that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater detail, he is kindly requested to contact the undersigned at his convenience.

The Commissioner is hereby authorized to charge any fee (including any claim fee or extension fee) which may be required to our Deposit Account No. 19-0741.

Respectfully submitted,

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By S. A. Bent

FOLEY & LARDNER LLP
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 672-5300
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicants
Registration No. 29,768

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